

REMARKS/ARGUMENTS

Claims 1, 4-9, 11-12, 15-20 and 34 are active. Independent Claims 1 and 12 have been revised to include, respectively, limitations of Claims 3 and 10; and Claims 14 and 21; and to refer to treatment of allergic conjunctivitis. Support for these amendments is found in the original claims and specification. No new matter is believed to have been added by the amendments. The Applicants respectfully request favorable consideration of this amendment and allowance of this application.

Rejection—35 U.S.C. §112, first paragraph

Claims 1-21 and 34 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. This rejection is moot in view of the amendments above. Independent Claims 1 and 12 both refer to macrolide compounds having a defined structure.

Rejection—Obviousness-type Double Patenting

Claims 1-21 and 34 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6 and 7 of U.S. Patent No. 6,872,383. The present invention is directed to treatment of allergic conjunctivitis. The claims of the cited patent are directed to treatment of dry eye condition and not to treatment of conjunctivitis. According to col. 1, lines 16-20 of the '383 patent "dry eye is defined to mean a condition wherein lacrimal fluid is less in amount or abnormal in quality, **with or without the presence of corneal and conjunctival lesion** (Yamada, M. et al., Folia Ophthalmol. Jpn., 43, 1289-1293 (1992))(emphasis added)". Dry eye is not necessarily associated with allergic conjunctivitis since it occurs independently of this disease. The present claims are directed to treatment of a disease distinct from the disorder covered by the claims of the prior patent and thus this rejection may be withdrawn.

Rejection—35 U.S.C. §102

Claims 1, 2, 5, 6, 7, 10, 11, 12, 13, 16, 17, 21 and 34 were rejected under 35 U.S.C. 102(b) as being anticipated by Asakura et al., U.S. Patent No. 5,368,865. The limitations of Claims 3 and 14, which were not rejected, have been incorporated into independent Claims 1 and 10. Accordingly, this rejection may now be withdrawn.

Rejection—35 U.S.C. §103

Claims 1-21 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno, U.S. Patent No. 6,872,383. This application and the '383 patent were invented by the same inventive entity: Ryuji Ueno. The prior patent does not render the claimed invention obvious because the target disorder (dry eye) in the '383 patent differs from allergic conjunctivitis, the target disease of the present claims. Conjunctivitis is an inflammation of the conjunctiva, which is a transparent membrane covering the eyeball and under surface of the eyelid. As discussed above "dry eye is defined to mean a condition wherein lacrimal fluid is less in amount or abnormal in quality, **with or without the presence of corneal and conjunctival lesion**". Unlike a dry eye condition, allergic conjunctivitis is frequently associated with tearing and watery discharge.

The '383 patent does not disclose, suggest or provide a reasonable expectation of success for treating allergic conjunctivitis using a compound of formula (I). However, assuming *arguendo* that the dry eye symptom was inevitably associated with allergic conjunctivitis, the prior art still does not provide a reasonable expectation of success that symptomatic treatment of dry eye would treat the underlying disease of allergic

conjunctivitis. For example, treatment of the symptom of dry eye could worsen the fluid discharge or tearing associated with allergic conjunctivitis.

Furthermore, the '383 patent does not suggest or provide a reasonable expectation of success for using an extremely low dose of the compound of formula (I) to treat allergic conjunctivitis, since the dosage ranges in the '383 patent (col. 8, lines 37 *ff.*) pertain to treatment of dry eye. On the other hand, the inventor has surprisingly discovered that use of a very low dosage range of the subject compounds treat allergic conjunctivitis. For example, Fig. 1 shows the ability of eye drops containing such a low dosage to suppress ocular itching in humans challenged with ocular allergens. There is no reasonable expectation of success for this result in the cited prior art. Accordingly, the Applicants respectfully submit that this rejection would not apply to the present claims.


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Conclusion

Upon review and consideration of the amendments and remarks above, the Applicants respectfully submit that this application shall be found in condition for allowance. An early notification to that effect is earnestly requested.

Respectfully submitted,

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